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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/805,813 | 03/22/2004 | Yi Feng Zheng | 9115 | 9960 |
| 34500 | 7590 | 05/17/2005 | EXAMINER | |
| | | | HAQ, SHAFIQU | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1641 | | |

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/805,813 | ZHENG ET AL. |
| | Examiner | Art Unit |
| | Shafiqul Haq | 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/22/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Although specific claims are cited and discussed in the rejection below, these rejections are also applicable to all other claims in which the noted problems/language occur.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 1,8,13, 14, 23, 48, 53, 58 and 60 recite the terms "non-poly(amino acid) label", "non-poly(amino acid) immunogenic carrier". It is not clear what "immunogenic carrier" or "label" is encompassed by the terms "non-poly(amino acid) immunogenic carrier" and non-poly(amino acid) label" as immunogenic carrier may include polysaccharides, nucleic acids or other non-protein substances and label may include various labeling agent such as fluorescent molecules (e.g. cyanine, fluorescein), radioactive substance, polynucleotide, electrophoretic tag etc. Therefore, it is unclear what immunogenic carrier or label is intended by the terms.
5. With respect to claims 1,13, 14, 23, 48, 53, 58 and 60, it is not clear what is encompassed by the term "functional group" as the term may include various activated terminal moieties such as sulfonic esters, phosphate esters, activated nitrites, aldehydes, ketones and alkylating agents for attaching haptens or carriers.

6. Claims 1,13, 14, 23, 48, 53, 58 and 60 recite the term "protecting group". It is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, the claims are vague and indefinite for not clearly defining the protecting group.
7. With respect to claims 30, 32, 40, 48 and 58 it is not clear "antibody" used in the method is raised against compound of what formula i.e against what hapten- immunogen conjugate?
8. With respect to claims 53 and 60, it is not clear what is encompassed by the term "amphetamine analog".
9. The recitation, "about 500" in claims 1,8,13, 14, 23, 48, 53, 58 and 60 is indefinite because the term does not establish how close the value should be to 500. The metes and bounds of the term are not defined. The term "about 500" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
10. The term "immunogenic protein" in claims 6, 19, 28, 53 and 60 are confusing. It is not clear whether the "immunogenic protein" conjugated with the compound is an immunogenic carrier or it itself acts as an immunogen?

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Heiman et al. (US 5,262,333)

Claims recite methods, compositions and kits for detecting amphetamine and methamphetamine in biological samples.

Heiman et al disclose a method and reagents for detection of amphetamine and methamphetamine including immunogen/conjugate and antibody raised against the immunogen.

The haptens and hapten conjugates disclosed by Heiman et al (see column 9, formula 1 and 3; column 16 formula 7; considering R=linking group or one heteroatom (e.g. O, N or S) and having a total of 1-6 carbon and Z, Q = as defined)) reads on the compounds of claims 1-19, 23-28, 48 53, 58 and 60 of the instant invention wherein R¹, R² = H or lower alkyl; L=bond or linking group; W, W', W"= as defined; v', v", v'''=0; y', y", y'''=bond and n=as defined.

As for immunogenic carrier, Heiman et al disclose poly(amino acid) (column 16, formula 7) conjugated with hapten for raising antibody against the immunogen (column 16, lines 26-31; column 38-40, examples 3, 4 and 5). As for label, Heiman et al disclose fluorescein compounds conjugated with hapten (column 9, formula 3) to be used as a tracer.

Heiman et al also disclose methods/assays for detection and quantitative determination of amphetamine derivatives (column 19, lines 1-15; column 21, lines 15-35).

Heiman et al further disclose reagent kit assembly for detection of amphetamine and methamphetamine in test samples such as biological fluids (claims 11-17).

The antibodies of claim 20-22, 29-32, 36, 40, 44, 48, 53, 58 and 60 are considered to be functionally equivalent of the antibodies of Heiman et al i.e. they have the same specificity. For product by process claims see MPEP 2113.

All the above disclosure reads on all the cited claims of the instant invention and therefore, the reference is deemed to anticipate the cited claims.

13. Claims 1, 3-23, 25-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Hui et al. (US 2003/0175995 A1)

Claims recite methods, compositions and kits for detecting amphetamine and methamphetamine in biological samples.

Hui et al disclose haptens and immunogens that are useful in the production of antibodies and detection of amphetamine derivatives.

The haptens and hapten conjugates disclosed by Hui et al (page 5, structure II

and paragraphs [0055-0057]); wherein Z= -L-X-Q and considering L= 1 heteroatom (e.g. O, N or S) and having a total of 1-6 carbon; X= -CO- and Q = as defined)) reads on the compounds of claims 1-19, 23-28, 48 53, 58 and 60 of the instant invention wherein R¹, R² = H or lower alkyl; L=bond or linking group; W, W', W"= as defined; v', v", v'''=0; y', y", y'''=bond and n=as defined.

Hui et al disclose immunogenic carrier (e.g. polypeptides, polysaccharides, nucleic acids, polymers, glycoproteins, proteins) (paragraphs [0055], [0056] and [0031]) or label (e.g. enzymes, fluorescent compounds, luminescent compounds, radioisotopes, protein binding partners) (paragraphs [0055] and [0033]), conjugated with the haptens for raising antibody against the immunogen and to be uses as a tracer.

Hui et al also disclose methods/assays for detection and quantitative determination of amphetamine derivatives (paragraphs [0067], [0068], [0077], [0035], [0055] and claims 42-50)

Hui et al further disclose reagent kit assembly for detection of amphetamine and methamphetamine in test samples such as biological fluids (paragraphs [0039], [0072], [0074], [0075] and [0076] and claims 31-34)

The antibodies of claim 20-22, 29-32, 36, 40, 44, 48, 53, 58 and 60 are considered to be functionally equivalent of the antibodies of Heiman et al (page 8) i.e. they have the same specificity. For product by process claims see MPEP 2113.

All the above disclosure reads on all the cited claims of the instant invention and therefore, the reference is deemed to anticipate the cited claims.

14. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US 2002/0090661 A1)

Claims recite methods, compositions and kits for detecting amphetamine and methamphetamine in biological samples.

Wang et al disclose novel tracers for detection of amphetamine derivatives.

The haptens and hapten conjugates disclosed by Wang et al (claims 1 and 3 wherein X= O, S, NH; R=linkage as defined and *= label and claim 5) reads on the compounds of claims 1-6 of the instant invention wherein R¹, R² = H or lower alkyl; L=bond or linking group; W= heteroatom; Z=label and n=1.

All the above disclosure reads on all the cited claims of the instant invention and therefore, the reference is deemed to anticipate the cited claims.

15. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (US 5,135,863)

Claims recite compounds, methods, compositions and kits for detecting amphetamine and methamphetamine in biological samples.

Hu et al disclose compounds and methods for detection of amphetamine methamphetamine.

The haptens and hapten conjugates disclosed by Hu et al (claims 1 to 4 wherein X= heteroatom such as O or S; R₁ and R₂= as defined; n=1 and R₃= H) reads on the compounds of claims 1-4 of the instant invention wherein R¹, R² = H or lower alkyl; L=bond or linking group; W= heteroatom; Z=H and n=1.

All the above disclosure reads on all the cited claims of the instant invention and

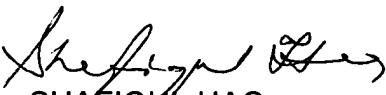
therefore, the reference is deemed to anticipate the cited claims.

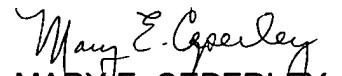
Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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